



Administrative and Operational Policies and Procedures

Page 1 of 7

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Section:	Research	Date Reviewed:	August 7, 2020
Title:	Individual Conflict of Interest Related to Human Subject Research	Date Revised:	August 7, 2020
Regulatory Agency:	FDA, HHS, PHS, NSF		

Reference: [#14.28 Responding to Allegations of Scientific Misconduct](#)

I. POLICY:

Individual interests may present real or perceived risks to the welfare and rights to human subject research and the integrity of the research at Children's Healthcare of Atlanta (Children's). Full disclosure and openness of potential and actual Conflicts of Interest (both financial and non-financial) must be reported, reviewed and managed. This policy applies to the interests of all individuals conducting or reviewing research at or otherwise involving Children's, as well as their Immediate Family, and covers all actual, apparent, perceived or potential Conflicts of Interest. Disclosure criteria will not vary regardless of the research study's funding sources or regulatory oversight.

Individuals conducting research at Children's are expected to comply with all applicable federal requirements pertaining to Conflict of Interest in their research activities. For research regulated by the Federal Drug Administration (FDA), there are requirements that apply to both the sponsor and the Investigator. Individuals conducting research at Children's are expected to comply with all applicable regulations whether the individual is the Investigator, the sponsor or both.

Definitions:

Conflict of Interest: Conflict of Interest refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an Investigator's professional judgment in the design, conduct, interpreting, oversight or reporting human subject research.

Research Conflict of Interest Committee (RCOIC): The RCOIC oversees the Conflict of Interest Program by providing advice, assistance, and review services on specific written Conflict of Interest policies and procedures and related activities.

Covered Party: For purposes of this policy, Covered Party refers to Investigators as defined below.

Financial Interest: Anything of monetary value or potential monetary value.

Immediate Family: For the purposes of this policy, this refers to spouses and dependent children.

Institutional Responsibilities: Activities that derive or descend from a staff member's professional standing or expertise.

Investigator: For the purposes of this policy, this refers to all study personnel engaged in the design, conduct, interpreting, oversight or reporting human subject research, including:

- Principal Investigators
- Research Coordinators
- Research Nurses
- Research Study Staff
- Students
- Sub-recipient Investigators

Non-Financial Interest: Being an executive or director of the agency or company sponsoring the research; or having an interest that an individual believes may conflict with his or her ability to objectively review a protocol or conduct a study.

Reimbursed or Sponsored Travel: For PHS sponsored research this includes all reimbursed or sponsored travel related to institutional responsibilities with the exception of travel sponsored by academic or governmental institutions. This does not include travel reimbursed or sponsored by the following:

- US Federal, state or local governmental agency
- US Institution of higher education
- US Academic teaching hospital
- US Medical Center, or
- a Research Institute affiliated with a US Institution of higher education

Significant Financial Interest:

Significant Financial Interest (SFI) means any financial interest consisting of one or more of the following interests of an Investigator or Family Member that reasonably appears to be related to the individual's institutional responsibilities.

- A. Remuneration or honoraria received from entities if valued at more than \$5,000
- B. Intellectual Property rights, interests and licensing fees (i.e., patents, copyrights, etc.) and/or royalties

- C. ownership interests (i.e., stock/options, dividends, equity) that are valued at more than \$5,000
- D. any ownership interests (i.e., stock/options, dividends, equity) in privately held entities (i.e., start-up companies, LLC's)
- E. holding any management position (e.g., director, officer, trustee, management employee) in a non-Children's entity
- F. Any compensation that could be affected by the outcome of the research study;
- G. Reimbursed or sponsored travel related to institutional responsibilities in PHS sponsored research

II. PROCEDURE:

1. Disclosure Process:

- a. Each time a new research study is submitted for review and approval, the Investigator shall disclose any SFI that are directly or indirectly related to the research study or the Investigator's responsibilities to the Institution, including, but not limited to, the name of the entity involved, the nature of the interest, the dollar amount or method for calculating future dollar amounts associated with such potential Conflict of Interest and a description of how the interest relates to the research. The Investigator may request, and the Compliance Office shall provide upon such request, a description of how and to what extent the information disclosed will be handled or shared.
- b. Annually and during the conduct of a research study, if any new Financial Interests or Non-Financial Interests are obtained by an Investigator that the Investigator would have been required to disclose if in existence at the time of submission for IRB approval or other interest that may be construed to be a Conflict of Interest, the Investigator will update their disclosures. This is particularly important if there is any change in the Investigator's personal financial or fiduciary status with respect to the potential Conflict of Interest.
- c. Investigators conducting PHS sponsored research must also disclose reimbursed or sponsored travel related to institutional responsibilities. Information submitted should include the purpose of the trip, the identity of the sponsor or organizer, the destination and the duration of the trip.
- d. The Investigator shall also disclose any potential Conflict of Interest to (1) state and federal officials as may be required by statute or regulations, (2) research funders or sponsors, (3) all researchers, students and trainees at Children's working with the Investigator on the research study, (4) the editors of any

- publication to which a Covered Party submits a manuscript of the research, (5) in any substantive public communication of the research results, whether oral or written, and (6) the human subjects of the research study. Additionally, for research regulated by the U.S. Food and Drug Administration (FDA), study personnel are required to disclose Conflicts of Interest to the FDA and the Children's Clinical Research Department at the conclusion of the study and one (1) year after. Any such disclosure shall specify the presence of the Conflict of Interest, an indication that additional information is available regarding the details of the Conflict of Interest and how it is being managed and how that information can be reasonably obtained by those to whom the disclosure is being made.
- e. Third parties may report alleged Conflicts of Interest, in writing to or calling, the Compliance or by calling the Compliance Hotline (877-373-0126) or by filing online at www.choa.alertline.com. Reports by a third party will be held in confidence and will follow the Children's Administrative and Operational Policy [#1.04 Problem Reporting and Non-Retaliation](#).
2. **Review of Disclosures:** Disclosures submitted are reviewed by the Compliance Office. If the Children's Compliance Office identifies a potential Conflict of Interest based on the information submitted, it will forward the appropriate documentation for review by the Children's RCOIC. The disclosure will be reviewed under one of three levels: Administrative, Expedited or by Full Committee. In reviewing the materials, the RCOIC will apply a rebuttable presumption against participation in human subjects' research by an Investigator with a Conflict of Interest. Such presumption may be overcome by "Compelling Circumstances," as defined below. The RCOIC will review the documentation and determine if a Conflict of Interest exists and recommend what conditions or restrictions, if any, should be imposed to manage, reduce or eliminate the Conflict of Interest. This recommendation will be forwarded to the Children's IRB Office and communicated to the Principal Investigator and/or Institutional Official.

"Compelling Circumstances" may exist that justify the Covered Party's participation in or oversight of the human subject research and impose conditions that effectively eliminate any significant risk to the safety of human subjects and preserve the integrity of the research data. The following shall be considered in making such a determination:

- the stage of the research
- any special insights, knowledge, perseverance, laboratory resources or special patient populations of the Investigator
- the best interests of the patients who could benefit from the research study
- the nature of the science
- the nature of the interest

- how closely the Investigator's interest is related to the human subjects' research study at issue
- the degree to which the interest may be affected by the human subject's research or the results thereof
- the level of risk involved to human subjects in the research study

Recommendations/Management Plans may include the following:

- a. The research study is permitted with no requirement for modification because the disclosed information does not represent a possible source of unreasonable bias or inappropriate activity.
- b. The research study is permitted with the implementation of one (1) or more modifications to preclude unreasonable levels of bias or inappropriate activities, with appropriate follow-up and review by the RCOIC and Children's IRB. Possible modifications may include, but are not limited to:
 - i. Internal and external disclosure of relevant information;
 - ii. Reformulation of the research work plan;
 - iii. Close monitoring of the research study by independent reviewers (e.g., Data Safety and Monitoring Board);
 - iv. Reduction of Financial Interest or removal of fiduciary role;
 - v. Termination of a study personnel's involvement in the research study;
 - vi. Severance of outside relationships (with supporting documentation or attestation) that pose Conflicts of Interest;
 - vii. Implementation of measures and protective factors in the design of the study to minimize potential bias, such as multiple Investigators, blinding, or objectives/endpoints; and
 - viii. Restriction on Investigator's role (e.g., cannot conduct the informed consent process or data analysis or a restriction as to the Investigator's involvement in certain stages).
- c. The research study is prohibited from being conducted at or involving Children's due to an unacceptable Conflict of Interest.

The research study cannot be approved by the IRB or funding cannot be dispersed until the RCOIC determines that the Conflict of Interest is managed, reduced or eliminated. The IRB has the final authority to decide whether the potential Conflict of Interest and its management, if any, allows the research study to be approved. All management plans may include monitoring responsibilities and enforcement procedures as well as potential sanctions.

2. **Committee Membership**: The Children's RCOIC membership may be comprised of the following voting members: Chief Academic Officer, General Counsel, Chief



Compliance Officer, the Chief Physician Officer, and one or more Investigators. The RCOIC may consult with other parties as needed including health care providers, senior leadership, finance or unaffiliated individuals in the community. The Vice President of Research and Academic Affairs Director of Research and the Compliance Consultant may attend as non-voting members.

3. **Record Collection and Retention:** Children's Compliance Office and the RCOIC will seek information on Conflicts of Interest only on a need-to-know basis and only as relevant to the research study under review. Records relating to Conflicts of Interest will be kept for a minimum of three (3) years after the termination of IRB approval or two (2) years after the date of approval of the application of the drug, biologic, or device, or whichever is the longest period. The confidentiality of the Covered Party's private investments and personal finances will be protected. Information requested shall relate only to financial relationships that might influence the Covered Party's objectivity in conducting the research or creating the intellectual property. Examples of requested information are:
 - Records showing any Financial Interest or arrangement paid to Covered Party by sponsor of research study
 - Records showing disclosed payments made by sponsor to Covered Party
 - Records showing any Financial Interests held by Covered Party
4. **Appeals Process:** The Covered Party may submit an appeal of the RCOIC determination to the Children's RCOIC. The RCOIC may seek expert opinions from individuals within or outside the Children's system. Any opinions will be reviewed by the RCOIC. The RCOIC will reconsider the research study in view of any expert opinions and report its conclusion to the Children's IRB Office, the Principal Investigator, and the Compliance Officer.
5. **Failure to Disclose:** Failure to disclose a Conflict of Interest, including refusal to sign a disclosure statement or furnishing false, misleading or incomplete information, will lead to sanctions by Children's in accordance with the Children's Administrative and Operational Policy [#14.28 Responding to Allegations of Scientific Misconduct](#). Sanctions may range from administrative intervention, termination of the research study, disciplinary action including loss of the right to perform research and/or termination of employment.

Violations of federal or state statutes and guidelines regarding Conflicts of Interest shall be handled according to federal or state laws and requirements. For sponsored research, violations shall be reported to the study sponsor.
6. **Education:** Education on financial Conflicts of Interest will be required of Investigators prior to engaging in research related to a PHS funded grant, cooperative agreement or contract and at least every four (4) years. Additionally, education is required immediately when:



- a. Financial Conflict of Interest policies are revised to reflect a change in Investigator requirements;
 - b. An Investigator is new to the organization; and
 - c. An Investigator is non-compliant with financial Conflict of Interest policies.
- 7. Reporting and Public Access:** Children's shall report all identified Conflicts of Interest as required by federal or state laws, rules and regulations, and Children's shall respond to any requestor for such information in writing within five (5) business days of such request or such shorter time as may be required by law.
- 8. Retrospective Review:** Children's will conduct a retrospective review in cases where there is documented non-compliance with federal or state laws, rules or regulations and shall identify and report on the impact of any bias found and the actions Children's has taken in response to such findings, all as required by law.

III. REFERENCES:

21 CFR 54 (a)(b), 2(f)

21 CFR 56.107

42 CFR 50

45 CFR 46

45 CFR 94

NIH Guidelines (A Guide to Preventing Conflicts of Interest in Human Subjects Research at NIH) – January 2005, August 2011

FDA Guidance (Financial Disclosure by Clinical Investigators) – March 2001

HHS Guidance (Financial Relationships and Interests in Research Involving Human Subject: Guidance for Human Subject Protection) – May 2004, 2011

Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research (AAMC-AAU)